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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,132	06/20/2003	Anthony P. Shuber	E0411.70037US00	4962

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EXAMINER	
AEDER, SEAN E	
ART UNIT	**PAPER NUMBER**
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,132	SHUBER, ANTHONY P.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8,10,11,13,14,17-21,23,24,27-30 and 32* is/are pending in the application.

4a) Of the above claim(s) *10, 13, 23, and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-8, 11, 14, 17-21, 24, 27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 10/26/06 in response to the Office Action of 4/21/06 are acknowledged and have been entered.

Claims 1, 4-8, 10, 11, 13, 14, 17-21, 23, 24, 27-30, and 32 are pending.

Claims 10, 13, 23, and 32 are withdrawn.

Claims 1, 4, 7, 11, 14, 17, and 24 have been amended by Applicant.

Claims 1, 4-8, 11, 14, 17-21, 24, and 27-30 are currently under examination.

The text of those sections of Title 35 U.S.C. code not included in this Office Action can be found in a prior Office Action.

Rejections Withdrawn

The rejection of claims 1, 4-8, 11, 14, and 17-21 under 35 U.S.C. 112 first paragraph, for failing to comply with the enablement requirement, is withdrawn in view of amendments. However, it is noted that claims 24 and 27-30 remain rejected under 35 U.S.C., first paragraph, for failing to comply with the enablement requirement.

The rejection of claims 1, 4, 6, 7, 11, 14, 17, 19, 20, 24, 28, and 29 under 35 U.S.C. 102(b), as being anticipated by Shuber et al (US 6,268,136 B1), is withdrawn in view of amendments.

The rejection of claims 1, 4-8, 11, 14, 17-21, 24, and 27-30 under 35 U.S.C., second paragraph, for being indefinite, is withdrawn in view of amendments.

Response to Arguments

35 USC § 112, first paragraph (enablement rejection)

Claims 24 and 27-30 remain rejected under 35 U.S.C. first paragraph, for failing to comply with the enablement requirement. While being enabling for a method of screening a patient for the presence of colon cancer and a method of screening for abnormally proliferating colon cancer cells comprising methods using a stool sample, the specification does not reasonably provide enablement for a method of screening a patient for the presence of *any type of disease* using *any type of sample comprising shed cells or shed debris*, screening a patient for *any type of abnormally proliferating cells* using *any type of sample comprising shed cells or shed debris*, and a method of diagnosing *the general state of health of a patient* using *any type of sample comprising shed cells or shed debris*.

The Office Action of 4/21/06 contains the following text:

"The specification teaches a method of screening a patient for the presence of colon cancer and a method of screening for abnormally proliferating colon cancer cells comprising methods using a stool sample (pages 8-23, in particular).

One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to a method of screening a patient for the presence of *any type of disease* using *any type of sample comprising shed cells or shed debris*, screening a patient for *any type of abnormally proliferating cells* using *any type of sample comprising shed cells or shed debris*, and a method of diagnosing the *general*

state of health of a patient using *any type of sample comprising shed cells or shed debris.*"

In response to the Office Action of 4/21/06, Applicant amended claims to recite "colorectal cancer" and "stool sample".

The amendments to the claims have been carefully considered, but are not deemed persuasive to enable claims 24 and 27-30. Claims 27-30 depend on claim 24, which recites: "A method **for diagnosing the health of a patient**, comprising the steps of: measuring a quantitative amount of genome equivalents of patient genomic DNA in a stool sample comprising shed cells or cellular debris; and performing an assay on a sample from the patient if the amount of genome equivalents is above a predetermined threshold amount of genome equivalents, wherein the state of health of the patient is evaluated to determine if the patient has colorectal cancer". Thus, claim 24 is drawn to determining every health aspect of a patient, comprising performing some kind of assay on just any sample from a patient if the amount of genomic DNA in a patient's stool is above a certain level.

If an assay is to be used to identify every aspect of the health of a patient, every aspect of the health of a patient must be identified in some way with the assay. For example, Tockman et al (Cancer Res., 1992, 52:2711s-2718s) teach considerations necessary in bringing a cancer biomarker (intermediate end point marker) to successful clinical application. Tockman et al teaches that prior to the successful application of newly described markers, research must validate the markers against acknowledged disease end points, establish quantitative criteria for marker presence/absence and

confirm marker predictive value in prospective population trials (see abstract). Early stage markers of carcinogenesis have clear biological plausibility as markers of preclinical cancer and if validated (emphasis added) can be used for population screening (p. 2713s, col 1). The reference further teaches that once selected, the sensitivity and specificity of the biomarker must be validated to a known (histology/cytology-confirmed) cancer outcome. The essential element of the validation of an early detection marker is the ability to test the marker on clinical material obtained from subjects monitored in advance of clinical cancer and *link* those marker results with subsequent histological confirmation of disease. This irrefutable link between antecedent marker and subsequent acknowledged disease is the essence of a valid intermediate end point marker (p. 2714, see Biomarker Validation against Acknowledged Disease End Points). Clearly, prior to the successful application of newly described markers, markers must be validated against acknowledged disease end points and the marker predictive value must be confirmed in prospective population trials (p. 2716s, col 2). In the instant specification, methods comprising a measure of nucleic acids in stool samples, a measure of mutations in stool samples, and colonoscopies have been shown to predictably diagnose colon cancer (pages 8-23). However, the claimed methods would not predictably detect any and every aspect of a patient's health.

In view of the teachings above and the lack of guidance, workable examples and or exemplification in the specification, it would require undue experimentation by one of

skill in the art to determine with any predictability, that the method would function as broadly claimed.

35 USC § 103(a)

Claims 1, 4-8, 11, 14, 17-21, 24, and 27-30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Shuber et al (US 6,268,136 B1) in view of Ahlquist et al (Gastroenterology, 2000, 119:1219-1227) and Hromadnikova et al (BMC Pregnancy and Childbirth, 5/28/02, 2(4):1-5) for the reasons stated in the Office Action of 4/21/06 and for the reasons set-forth below.

The Office Action of 4/21/06 contains the following text:

"Shuber et al teaches methods for screening a patient for the presence of colorectal cancer or pre-cancerous colorectal lesions, screening a patient for abnormal proliferating cells associated with colorectal cancer or pre-cancerous colorectal lesions, and a method of diagnosing the state of health of a patient relating to colorectal cancer or pre-cancerous colorectal lesions (see abstract and columns 2 and 3, in particular). The methods taught by Shuber et al comprise the steps of measuring a quantitative amount of genomic DNA in a stool sample, and identifying the patient as a candidate for additional disease testing or identifying patients with a positive screen if the amount of nucleic acid is above a predetermined threshold amount (see column 2 lines 56-65, in particular). Shuber et al further teaches methods of performing an assay to detect ras mutations if a patient is identified as a candidate for additional disease testing or if a

positive screen is determined (see column 5 lines 33-48 and column 6 lines 53-56, in particular)

.... Ahlquist et al teaches methods for screening a patient for the presence of colon cancer comprising measuring a quantitative amount of genomic DNA in a stool sample, and identifying the patient as a candidate for additional disease testing or identifying patients with a positive screen if the amount of nucleic acid is above a predetermined threshold amount (pages 1221-1224, in particular). Ahlquist et al teaches colorectal cancer patients have higher fecal DNA yields than controls (page 1220 left column). Ahlquist et al further teaches methods of performing a DNA integrity assay (pages 1221-1222, in particular) and an assay to detect ras, p53, and BAT-26 mutations (page 12221 right column, in particular). The method of determining DNA integrity taught by Ahlquist et al comprises two technicians that independently visually determined the amount of high-integrity DNA (page 1222 left column, in particular). Ahlquist et al further teaches colonoscopies as an expensive means of detecting colon cancer (page 1219 right column, in particular). Ahlquist et al further teaches that fecal occult blood testing may detect cancers at an early stage; however, many cancers and most premalignant adenomas do not bleed and are missed (page 1219 right column, in particular). Thus, Ahlquist et al indicate that the sensitive and specific markers they teach would improve the effectiveness and efficiency of stool screening prior to colonoscopy (page 1219 right column, in particular).

Hromadnikova et al teaches a quantitative method of comparing amounts of DNA between samples comprising determining the number of genome equivalents (page 2 right column, in particular).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the methods of screening a patient for the presence of a disease, screening a patient for abnormal proliferating cells, and diagnosing the state of health of a patient using methods taught by Shuber et al with methods of detecting additional mutations associated with colorectal cancer, performing DNA integrity assays, and performing colonoscopies using methods taught by Ahlquist et al. Further, one would have been motivated to do so because Shuber et al stresses the importance of analyzing nucleic acids for genes that have mutations in colorectal cancer. One of skill in the art would be further motivated to combine the teachings of Ahlquist et al with the teachings of Shuber et al because combining multiple assays of detection is know to enhance the accuracy of screening and diagnosis. Further, one would have been motivated to perform colonoscopies after the other screening methods because one of skill in the art would want to perform less expensive and less invasive methods before performing more expensive and more invasive methods such as colonoscopies. Further, one of skill in the art would have a reasonable expectation of success in performing the claimed screening methods since detection of mutations, DNA integrity assays, and colonoscopies are well known and conventional in the art. Further, it would have been obvious to quantitate methods involved in comparing amounts of DNA between samples comprising determining the number of genome

equivalents as taught by Hromadnikova et al. Further, one would have been motivated to do so because using the quantitative method taught by Hromadnikova et al would be an effective way of normalizing data between multiple assays. Further, determining the number of genome equivalents as taught by Hromadnikova et al would reduce technical errors that would occur with methods of Ahlquist et al. Further, one of skill in the art would have a reasonable expectation of success in determining the number of genome equivalents since determining the number of genome equivalents in a sample is well known and conventional in the art. Further, it would have been *prima facie* obvious to one of ordinary skill in the art to compare DNA yields from patients with colorectal cancer than from controls *prior* to performing the DNA integrity assay or detection of mutation assay. Further, one would be motivated to do so because one would routinely determine the amount of total DNA in a sample in preparation for performing DNA integrity assays or assays detecting mutations and the method of Shuber et al teaches quantitating the DNA before performing methods of detecting mutation."

In response to the Office Action of 4/21/06, Applicant amended the claims and argues that Shuber et al (US 6,268,136 B1) in view of Ahlquist et al (Gastroenterology, 2000, 119:1219-1227) and Hromadnikova et al (BMC Pregnancy and Childbirth, 5/28/02, 2(4):1-5) "does not teach measuring a quantitative amount of genome equivalents of patient genomic DNA in a stool sample and comparing it to a predetermined threshold amount of genome equivalents".

The amendments to the claims and the arguments found in the Response of 10/26/06 have been carefully considered, but are not deemed persuasive. The

methods taught by Shuber et al comprise the steps of measuring a quantitative amount of genomic DNA in a stool sample, and identifying a patient as a candidate for additional disease testing or identifying patients with a positive screen if the amount of nucleic acid is above a predetermined threshold amount. Ahlquist et al also teaches methods for screening a patient for the presence of colon cancer comprising measuring a quantitative amount of genomic DNA in a stool sample, and identifying the patient as a candidate for additional disease testing or identifying patients with a positive screen if the amount of nucleic acid is above a predetermined threshold amount (pages 1221-1224, in particular). Hromadnikova et al teaches a quantitative method of comparing amounts of DNA between samples comprising determining the number of genome equivalents (page 2 right column, in particular). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the methods of Shuber et al and/or Ahlquist et al with Hromadnikova to measure a quantitative amount of genome equivalents of patient genomic DNA in a stool sample and comparing it to a predetermined threshold amount of genome equivalents. Further, one would have been motivated to do so because incorporating the quantitative method taught by Hromadnikova et al would be an effective way of normalizing data between multiple assays. Further, determining the number of genome equivalents as taught by Hromadnikova et al would reduce technical errors that would occur with methods of Ahlquist et al or Shuber et al. Further, one of skill in the art would have a reasonable expectation of success in determining the number of genome

equivalents since determining the number of genome equivalents in a sample is well known and conventional in the art.

35 USC § 103(a)

Claims 1, 4-8, 11, 14, 17-21, 24, and 27-30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlquist et al (Gastroenterology, 2000, 119:1219-1227) in view of Hromadnikova et al (BMC Pregnancy and Childbirth, 5/28/02, 2(4):1-5) for the reasons stated in the Office Action of 4/21/06 and for the reasons set-forth below.

The Office Action of 4/21/06 contains the following text:

"Ahlquist et al teaches methods for screening a patient for the presence of colon cancer comprising measuring a quantitative amount of genomic DNA in a stool sample, and identifying the patient as a candidate for additional disease testing or identifying patients with a positive screen if the amount of nucleic acid is above a predetermined threshold amount (pages 1221-1224, in particular). Alhlquist et al teaches colorectal cancer patients have higher fecal DNA yields than controls (page 1220 left column). Ahlquist et al further teaches methods of performing a DNA integrity assay (pages 1221-1222, in particular) and an assay to detect ras, p53, and BAT-26 mutations (page 12221 right column, in particular). The method of determining DNA integrity taught by Ahlquist et al comprises two technicians that independently visually determined the amount of high-integrity DNA (page 1222 left column, in particular). Ahlquist et al further teaches colonoscopies as an expensive means of detecting colon cancer (page

1219 right column, in particular). Ahlquist et al further teaches that fecal occult blood testing may detect cancers at an early stage; however, many cancers and most premalignant adenomas do not bleed and are missed (page 1219 right column, in particular). Thus, Ahlquist et al indicate that the sensitive and specific markers they teach would improve the effectiveness and efficiency of stool screening prior to colonoscopy (page 1219 right column, in particular).

... Hromadnikova et al teaches a quantitative method of comparing amounts of DNA between samples comprising determining the number of genome equivalents (page 2 right column, in particular).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to screening a patient for the presence of colon cancer or the abnormally proliferating cells of colon cancer by using methods taught by Ahlquist et al with the quantitative method of comparing amounts of DNA between samples comprising determining the number of genome equivalents as taught by Hromadnikova et al. Further, one would have been motivated to do so because using a quantitative method of comparing samples would reduce the technical errors that would occur with the method of Ahlquist et al, which uses highly subjective means of comparing samples. Further, one of skill in the art would have a reasonable expectation of success in performing the claimed method since comparing amounts of DNA between samples comprising determining the number of genome equivalents is well known and conventional in the art. Further, it would have been *prima facie* obvious to one of ordinary skill in the art to compare DNA yields from patients with colorectal

cancer than from controls *prior* to performing the DNA integrity assay or detection of mutation assay. Further, one would be motivated to do so because one would routinely determine the amount of total DNA in a sample in preparation for performing DNA integrity assays or assays detecting mutations."

In response to the Office Action of 4/21/06, Applicant amended the claims and argues that Alquist et al (Gastroenterology, 2000, 119:1219-1227) in view of Hromadnikova et al (BMC Pregnancy and Childbirth, 5/28/02, 2(4):1-5) "does not teach measuring a quantitative amount of genome equivalents of patient genomic DNA in a stool sample and comparing it to a predetermined threshold amount of genome equivalents".

The amendments to the claims and the arguments found in the response of 10/26/06 have been carefully considered, but are not deemed persuasive. Ahlquist et al teaches methods for screening a patient for the presence of colon cancer comprising measuring a quantitative amount of genomic DNA in a stool sample, and identifying the patient as a candidate for additional disease testing or identifying patients with a positive screen if the amount of nucleic acid is above a predetermined threshold amount (pages 1221-1224, in particular). Hromadnikova et al teaches a quantitative method of comparing amounts of DNA between samples comprising determining the number of genome equivalents (page 2 right column, in particular). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the methods of Ahlquist et al with Hromadnikova to measure a quantitative amount of genome equivalents of patient genomic DNA in a stool sample and

comparing it to a predetermined threshold amount of genome equivalents. Further, one would have been motivated to do so because incorporating the quantitative method taught by Hromadnikova et al would be an effective way of normalizing data between multiple assays. Further, determining the number of genome equivalents as taught by Hromadnikova et al would reduce technical errors that would occur with methods of Ahlquist et al. Further, one of skill in the art would have a reasonable expectation of success in determining the number of genome equivalents since determining the number of genome equivalents in a sample is well known and conventional in the art.

Provisional Double Patenting

Claims 1, 4-8, 11, 14, 17-21, 24, and 27-30 remain provisionally rejected, on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-7 of copending Application No 11/090479 in view of Alquist et al and Hromadnikova et al., for the reasons stated in the Office Action of 4/21/06. Applicant requests to defer substantive rebuttal of this rejection.

Nonstatutory Obvious Double Patenting

Claims 1, 4-8, 11, 14, 17-21, 24, and 27-30 remain rejected, on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over (a) claims 1-4 of U.S. Patent No. 6,919,174, in view of Alquist et al and Hromadnikova et al.; (b) claims 1-4 of U.S. Patent No. 6,964,846, in view of Alquist et al and Hromadnikova et al, (c) claims 1-4 of U.S. Patent No. 6,143,529, in view of Alquist et al

and Hromadnikova et al.; and (d) claims 1-4 of U.S. Patent No. 6,268,136, in view of Alquist et al and Hromadnikova et al., for the reasons stated in the Office Action of 4/21/06 and for the reasons set-forth below.

The Office Action of 4/21/06 contains the following text:

"The claims of U.S. Patent No. 6,919,174 B1 are drawn a method of screening a patient for cancer or precancer comprising a DNA integrity assay.

... The claims of U.S. Patent No. 6,964,846 B1 are drawn a method of screening a patient for cancer or precancer comprising a DNA integrity assay.

... The claims of U.S. Patent No. 6,143,529 are drawn a method of screening a patient for cancer or precancer comprising a DNA integrity assay. The claims are further drawn to detecting mutations in order to diagnose colon cancer.

... Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to screening a patient for the presence of colon cancer or the abnormally proliferating cells of colon cancer by using methods of claims the claims of U.S. Patent No. ... with the other methods of screening for colon cancer as taught by Ahlquist et al and with the quantitative method of comparing amounts of DNA between samples comprising determining the number of genome equivalents as taught by Hromadnikova et al. Further, one would have been motivated to do so because combining screening methods would give rise to a more accurate diagnosis and using a quantitative method of comparing samples would reduce the technical errors. Further, one of skill in the art would have a reasonable expectation of success in performing the claimed method since the screening methods taught by

Ahlquist et al and methods of comparing amounts of DNA between samples comprising determining the number of genome equivalents are well known and conventional in the art. Further, it would have been *prima facie* obvious to one of ordinary skill in the art to compare DNA yields from patients with colorectal cancer than from controls *prior* to performing the DNA integrity assay or detection of mutation assay. Further, one would be motivated to do so because one would routinely determine the amount of total DNA in a sample in preparation for performing DNA integrity assays or assays detecting mutations."

In response to the Office Action of 4/21/06, Applicant argues that the cited claims taken alone, or in view of Alquist et al (Gastroenterology, 2000, 119:1219-1227) and Hromadnikova et al (BMC Pregnancy and Childbirth, 5/28/02, 2(4):1-5), "fail to teach or suggest measuring a quantitative amount of genome equivalents of patient genomic DNA in a stool sample and comparing it to a predetermined threshold amount of genome equivalents".

The amendments to the claims and the arguments found in the response of 10/26/06 have been carefully considered, but are not deemed persuasive. The cited claims teach measuring a quantitative amount of nucleic acid greater than 200bp in a stool sample and comparing it to an amount of nucleic acid greater than 200bp "expected to be present in a healthy patient" (see claim 1 of US Patent 6964846 B1, for example). Clearly, much of the nucleic acid greater than 200bp in a stool sample would be genomic DNA. Further, expressing a measurement of genomic DNA using a specific unit of measure, such as "genome equivalents", does not make a measurement novel.

New Rejections Necessitated by Amendments

Claims 24 and 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 and dependent claims 27-30 are rejected because claim 24 is incomplete for omitting essential steps, such omission amounting to a gap between the steps. Amended claim 24 recites "...wherein the state of health of the patient is evaluated to determine if the patient has colorectal cancer"; however, it is not clear what kind of evaluation would lead one to determine that a patient has colorectal cancer. Thus, there is a missing step involving correlating the evaluation of specific results to a specific diagnosis. See MPEP § 2172.01.

Summary

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. ' 1.136(a). A shortened statutory period for response to this Final Action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this Final Action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. '1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than six months from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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